

K112309
Page 1 of 2

Section 5: 510(k) Summary

510(k) Summary

SEP - 2 2011

Prepared: August 10, 2011

Submitter/Holder:

Company Name: CANON INC.
Company Address: 30-2 Shimomaruko 3-chome, Ohta-ku
Contact Person: Tokyo 146-8501, Japan
Phone Number: Naoyasu Asaka
Fax Number: 81-3-3758-2111
81-3-5482-3960

Proposed Device:

Reason For 510(k): New Model
Trade Name: Canon
Model Name: DIGITAL RADIOGRAPHY CXDI-80C Wireless
Classification Name: DIGITAL RADIOGRAPHY CXDI-80G Wireless
FDA 510(k) #: 90MQB, Solid State X-ray Imager
To be assigned

Predicate Device:

Trade Name: Canon
FDA 510(k) #/Model Name: K103591/ DIGITAL RADIOGRAPHY CXDI-401G
Classification Name: K102012/ DIGITAL RADIOGRAPHY CXDI-70C Wireless
90MQB, Solid State X-ray Imager

Description of Device:

The DIGITAL RADIOGRAPHY CXDI-80C Wireless and CXDI-80G Wireless are solid state x-ray imagers which have 27x35cm imaging area. The DIGITAL RADIOGRAPHY CXDI-80C/80G Wireless intercept x-ray photons and the scintillator of the CXDI-80C/80G Wireless emit visible spectrum photons that illuminate an array of photo-detectors that create electrical signals. After the electrical signals are generated, it is converted to digital value, and the images will be displayed on monitors. The digital value can be communicated to the operator console via wiring connection or wireless.

Intended Use:

The DIGITAL RADIOGRAPHY CXDI-80C Wireless and CXDI-80G Wireless provide digital image capture for conventional film/screen radiographic examinations. These devices are intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. These devices are not intended for mammography applications.

Comparison to Predicate:

The amorphous silicon array specifications of CXDI-80C Wireless and CXDI-80G Wireless, imaging principle and intended use are the same as those of the predicate devices (CXDI-70C Wireless and CXDI-401G).

K112309

Page 2 of 2

Section 5: 510(k) Summary

Performance testing:

The Electrical safety, Electromagnetic compatibility and other performance testings were performed on these devices which demonstrated that these devices are safe and effective, and are equivalent to the predicate devices.

Conclusion:

The Performance Data demonstrate that CXDI-80C Wireless and CXDI-80G Wireless are as safe and effective as the predicate devices (CXDI-70C Wireless and CXDI-401G). Based on the information in this submission, similarity to the predicate devices, and the results of our design control activities and non-clinical testing, it is our opinion that the DIGITAL RADIOGRAPHY CXDI-80C Wireless and CXDI-80G Wireless described in this submission are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Mr. Naoyasu Asaka
Staff manager
Canon Inc.
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JAPAN

AUG 23 2013

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Re: K112309

Trade/Device Name: Canon/Digital Radiology, CXDI-80C Wireless,
Canon/Digital Radiology, CXDI-80G Wireless

Regulation Number: 21 CFR 892.1680

Regulation Name: Stationary x-ray system

Regulatory Class: II

Product Code: MQB

Dated: August 10, 2011

Received: August 11, 2011

Dear Mr. Asaka:

This letter corrects our substantially equivalent letter of September 13, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

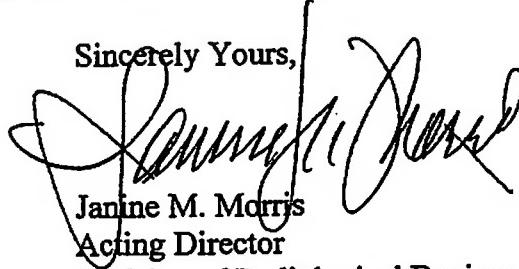
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K112309

Indications for Use

510(K) Number (if known): K112309

Device Name: CXDI-80C Wireless and CXDI-80G Wireless

Indications for Use:

DIGITAL RADIOGRAPHY CXDI-80C Wireless and CXDI-80G Wireless provide digital image capture for conventional film/screen radiographic examinations.

These devices are intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

These devices are not intended for mammography applications.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Page 1 of 1

Mary S Pastil
Mary S. Pastil, R.T., M.S.
Manager, Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112309